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The effect of voltaren on the initial acclimation to rigid gas permeable contact lenses

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Abstract

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METHODS: Thirty optometry student volunteers were divided into two groups, with one being an experimental group and the other being a control group. Prior to study commencement, each group was required to complete a questionnaire regarding how they perceived they would adapt to rigid gas permeable lenses in each of nine categories. The categories tested were dryness, itching, pain, lens movement, lacrimation, blinking, overall comfort, overall adaptation, and overall satisfaction. Upon study commencement, the experimental group received one drop in each eye of Voltaren 30 minutes, 15 minutes, and just prior to lens insertion. The control group received drops of the ocular lubricating drop Genteal following the same regimen as the experimental group. Lenses were inserted in both eyes of each subject in both groups after the third drop instillation. Each group was allowed to acclimate to their lenses for one hour at which time each group received one more of their respective drops in both eyes. Both groups continued to acclimate to the lenses for one more hour. At the end of the second hour both groups were required to complete a questionnaire regarding how they felt they adapted to the rigid lenses. Lenses were then removed upon completion of the adaptation questionnaire.

RESULTS: Repeated measures ANOVA with significance at $p < .05$ level showed no statistical difference between Voltaren and Genteal in all nine categories tested.

CONCLUSION: 0.1% diclofenac sodium shows no benefit over Genteal in aiding initial acclimation to rigid gas permeable contact lenses.

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voltaren, rgp, corneal sensitivity, contact lens acclimation

Subject Categories

Optometry

The Effect of Voltaren on the Initial Acclimation to Rigid Gas Permeable Contact Lenses

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Advisor:
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The Effect of Voltaren on the Initial Acclimation to Rigid Gas Permeable Contact Lenses

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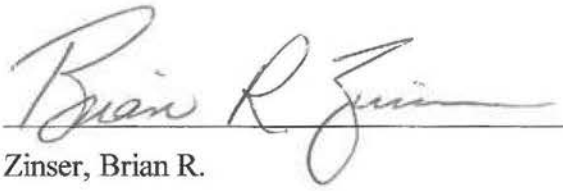
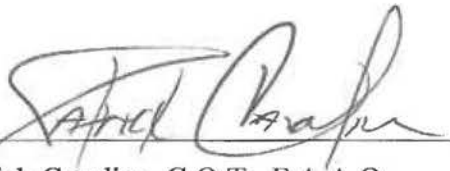
Yun, Sylvia

Author 

Zinser, Brian R.

Advisor 

Patrick Caroline, C.O.T., F.A.A.O.

Date December 20, 2002

Researcher Biographies

Brian Zinser was born and raised in Northern California. He received a Bachelor of Arts degree in Sociology from the University of California, Davis, in 1993. After working with troubled youth for a period of time after college, he decided to follow his lifelong dream of becoming an eye doctor. After spending three years at Portland State University completing the pre-requisite optometry coursework, Brian chose to attend Pacific University College of Optometry where he is a member of the graduating class of 2003.

Ruby Parmar was born and raised in Quesnel BC, Canada. She attended Simon Fraser University, Vancouver BC, Canada where she earned a Bachelor of Science degree in Biological Sciences. Ruby is a member of the Pacific University College of Optometry graduating class of 2003.

Sylvia Yun was born and raised in Seoul, Korea until her family immigrated to the United States when she was eight years old. Sylvia received her Bachelor of Science degree in Visual Science from Pacific University. She will be earning her Doctor of Optometry degree from Pacific University in 2003.

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Key Words:

Voltaren

RGP

Corneal sensitivity

Contact lens acclimation

Introduction:

Rigid gas permeable contact lenses have many advantages over soft contact lenses. They provide higher quality of vision, safety, and long-term comfort.[3] In addition, RGPs are more durable and require simple care systems. Despite the important advantages of rigid gas permeable lenses, the disadvantages of providing less initial comfort and longer adaptation period discourages practitioners and patients from the benefits of this lens modality. To overcome this initial trepidation, many clinicians have employed topical anesthetics, such as proparacaine, during initial lens fitting.[4] Although effective in providing initial patient comfort and satisfaction, these drugs are known to induce corneal toxicity and are contraindicated for long-term use.

Topical ophthalmic nonsteroidal anti-inflammatory drugs (NSAIDS) have become popular among eye care practitioners because they offer both anti-inflammatory and analgesic effects at the corneal surface with minimal adverse effects.[8] Diclofenac, a member of the phenylacetic acid group of NSAIDS, is believed to be effective in inhibiting the cyclooxygenase pathway which leads the conversion of arachadonic acid into the pain and inflammatory mediating prostaglandins, prostacyclin, thromboxane, and leukotrienes.[1,10,14,15] For this reason it is commonly prescribed for the management of pain and inflammation associated with a variety of conditions including post cataract extraction, refractive surgery, corneal abrasions, recurrent corneal erosions, rust ring removal, episcleritis, allergic conjunctivitis, phlyctenular conjunctivitis, and corneal ulcers. [1,9,11,12,14,15] It can also be postulated that if effective, diclofenac would have a clear advantage as being a safer modality in promoting initial rigid lens comfort.

With effective analgesic and anti-inflammatory properties, it comes as no surprise that diclofenac has captured the interest of the contact lens community as a possible modality for initial rigid lens comfort. Surprisingly, a number of studies have shown that diclofenac sodium may actually be ineffective in providing any benefit to lens adaptation.[4,6,10] However, each study tested the effectiveness of diclofenac sodium based on QID dosing. This dosing regimen conflicts with research which has shown that diclofenac may be more effective with higher frequent dosing within a shorter time interval.[2,17,18] Based on the premise that the effectiveness of diclofenac sodium may increase with successive drops, we propose that a dosing regimen of three drops given at thirty minutes, fifteen minutes, just prior to, and one hour after lens insertion may be effective in promoting initial rigid gas permeable lens acclimation.

Methods:

Thirty optometry students were chosen to participate in this study based on five criterias: 1) Corneal astigmatism less than 3 diopters 2) No previous habitual RGP (hard) contact lens wear 3) No significant corneal trauma 4) No previous corneal surgery, including refractive error correction 5) No known allergies to non-steroidal anti-inflammatory drugs. Of the thirty participants, two groups of fifteen were randomly assigned as either test group or control group. Each of these groups were sub-divided into groups of five and randomly assigned to one of three researchers. Subjects from each group initially read and signed a release of liability. Corneal topography was performed using a Humphrey corneal topographer just prior to initiation of the experimental protocol. Paragon HDS CAD design rigid gas permeable contact lenses

with power of -3.00 diopters and 9.5 millimeter diameter were fit on each patient's flat keratometry reading. However, those subjects who were found to be between base curves were fit with the next flatter lens which was no more than 0.25 diopter flatter than their actual flat corneal curvature. Lenses were not fit to the eyes prior to the treatment regimen in order to prevent possible early adaptation. Subjects were asked to fill out a questionnaire regarding their perceptions about how a rigid contact lens would feel prior to beginning the experimental trial. The questionnaire asked the research subjects to rank on a scale of one to ten, one being very uncomfortable and ten being extremely comfortable, how rigid gas permeable lenses would feel to them in each of nine categories. The criteria questioned were dryness, itching, pain, lens movement, lacrimation, blinking, overall comfort, overall, adaptation, and overall satisfaction.

Each experimenter was issued one 5 ml bottle of diclofenac Sodium 0.1% (Voltaren™) and one 10 ml bottle of Genteal, each with the labels occluded to ensure subjects remained blinded to the type of drops they were receiving. The dosing regimen used was the same for both the experimental and control groups. Each subject received one drop in each eye at 30 minutes, 15 minutes, and just prior to lens insertion. Each subject acclimated to the lenses for one hour at which time one more drop was instilled in each eye. Subjects continued to wear the rigid lenses for one hour after the last drop. Subjects then filled out an adaptation questionnaire just prior to lens removal, which consisted of the same questions asked in the perception questionnaire. Subjects were excused from the study upon completion of the final questionnaire. Results were compiled and statistically analyzed.

Results:

Analysis of variance for repeated measures (ANOVA) was performed with significance determined at the $p > 0.05$ level. Results have been tabulated and presented below. Bold print notated with double asterisks indicates statistically significant findings.

Table 1

	Voltaren vs. Genteal		**Perception vs. Adaptation**		**Interaction Effects**	
	F-ratio	p value	F-ratio	p value	F-ratio	p value
Dryness	F(1,13) = 0.044	0.837	F(1,1) = 2.457	0.124	F(1,43) = 1.065	0.308
Itching	F(1,13) = 0.945	0.349	***F(1,1) = 11.112***	***0.002****	***F(1,43) = 5.047***	***0.030****
Pain	F(1,13) = 0.241	0.631	***F(1,1) = 72.390***	***0****	F(1,43) = 0.037	0.848
Lens Movement	F(1,13) = 0.220	0.647	F(1,1) = 0.300	0.587	F(1,43) = 0.263	0.610
Lacrimation	F(1,13) = 0.935	0.351	***F(1,1) = 40.101***	***0****	F(1,43) = 0.127	0.723
Blinking	F(1,13) = 1.365	0.265	***F(1,1) = 13.376***	***0.001****	F(1,43) = 0.803	0.375
Overall Comfort	F(1,13) = 0.293	0.597	***F(1,1) = 14.903***	***0****	F(1,43) = 0.000	0.984
Overall Adaptation	F(1,13) = 3.430	0.087	***F(1,1) = 28.242***	***0****	F(1,43) = 3.018	0.089
Overall Satisfaction	F(1,13) = 1.248	0.284	F(1,1) = 0.123	0.727	F(1,43) = 0.342	0.562

Discussion:

There were three areas of statistical importance that were evaluated during this study. The first was to examine whether or not there was statistically significant difference in perception between Voltaren and Genteal based on each subject's answers to the nine different criteria on two different questionnaires. The second test of statistical importance was to test whether or not the subjects demonstrated variance in answering each of the nine questions.

As can be seen in table 1, there was no statistical difference between the effect of Voltaren and Genteal in all nine categories tested. There are undoubtedly many reasons that Voltaren showed no significant effect over Genteal. One reason that is very important is the dosing regimen used. As opposed to previous studies which used QID dosing to evaluate the efficacy of Voltaren as an aid with patient acclimation to rigid contact lenses, this study focused on the evidence that corneal sensitivity is further decreased with each successive drop of Voltaren instilled over a short term period.[6,4] Although the effect of Voltaren seems to be compounded by each additional drop instilled, it seems that this effectiveness may be short lived. Studies have shown that corneal sensitivity returns to baseline within one hour of final dosing.[18] This may have had significant implication in this study when considering our subjects did not complete the second questionnaire until well over one hour past the final dosing. A second questionnaire asked just after the final dosing might have provided more information about the initial effectiveness of Voltaren. Another point to be considered is that even if Voltaren is shown to be effective just after drop instillation, the short duration of effect, and the subsequent need for serial dosing over short time spans, may make the use of Voltaren as an aid to RGP acclimation impractical for all but the most motivated and compliant patients.

A final point to consider is that the effect of Voltaren on decreasing corneal sensitivity has been documented yet is only one factor in many that would facilitate initial comfort in wearing rigid contact lenses. Equally important to initial lens comfort is the effect of Voltaren on the surrounding ocular adnexa, which has had little evaluation.

Interaction between the lid margin, palpebral conjunctiva, and rigid lens undoubtedly play a major role in perceived patient comfort and is certainly difficult, if not impossible, for patients to distinguish the exact type or locality of their symptoms. This may be an inherent flaw in study design as each category in the questionnaire has the potential to contaminate the others.

When analyzing within subject variance between questionnaires, Table 1 shows statistical significance between subject perception and adaptation for itching, pain, lacrimation, blinking, overall comfort, and overall adaptation. This finding suggests that each subject may have scored the same question on each questionnaire very differently but that difference quite possibly was nullified by an equal but opposite score from another subject. This would show overall as a statistically insignificant difference between subject groups even though there was much variance within subject groups. Subject bias could be one explanation for the variance within subjects. Although no subjects had previously worn rigid contact lenses as a modality for the correction of ametropia or ocular pathology, all thirty subjects chosen for this study were third year optometry students with experience in fitting and wearing rigid contact lenses as part of the optometry degree curriculum. Therefore, it is reasonable to suggest that their previous experiences with RGP lenses may have had a significant influence on their experiences during this study and therefore their responses to the questionnaires. Comparison studies with subjects who are completely inexperienced and unbiased toward RGP wear under the same experimental conditions would be enlightening.

Lastly, the interaction effects between trials was statistically significant for itching ($p = 0.030$) only. It is unclear why this question showed statistical significance

and the others did not, as the conditions were constant during each trial. It is assumed that the amount of itching during the answering of the first trial questionnaire influenced the amount of itching and the subsequent answer on the second questionnaire during the second trial. Again, there is no good explanation for the significance in this one area compared to the others tested.

Overall, the conclusion drawn from this study is that diclofenac sodium 0.1% (Voltaren) is no more effective in facilitating initial lens acclimation than Genteal. It is quite possible that the efficacy of Voltaren is short-lived and very dose dependant, which may limit its clinical usefulness.

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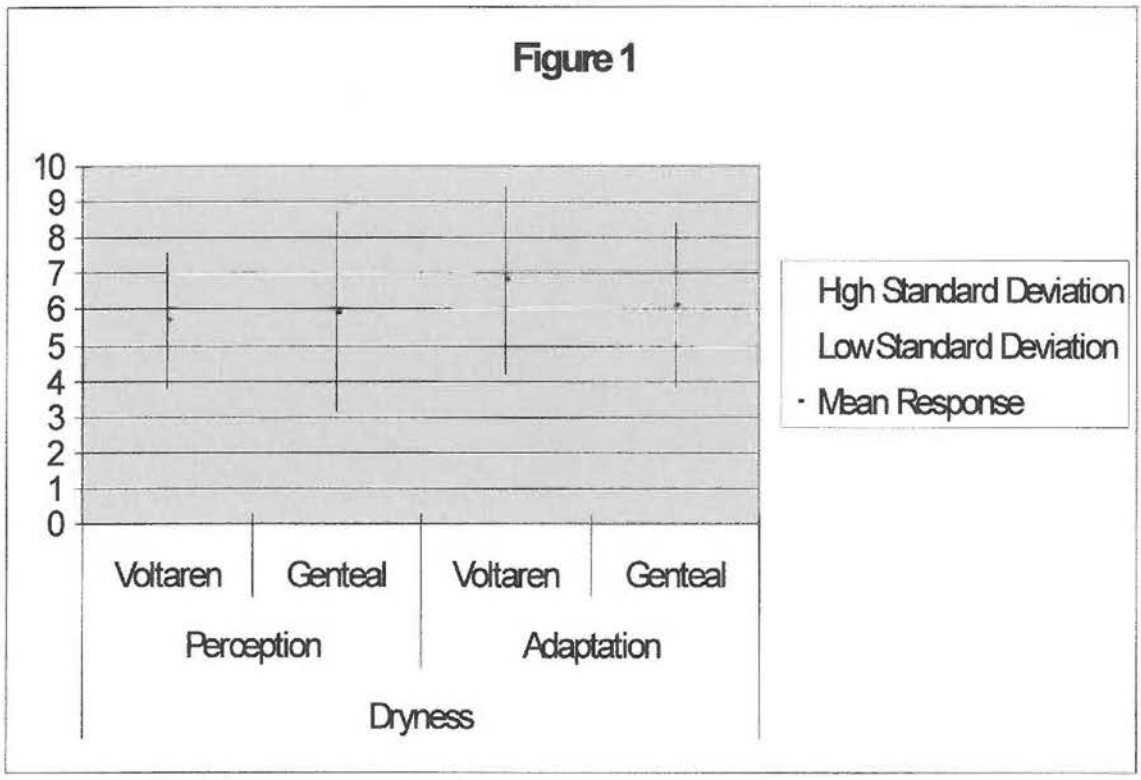
Appendix A

Figures 1 – 9

Perception Questionnaire

Adaptation Questionnaire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Voltaren
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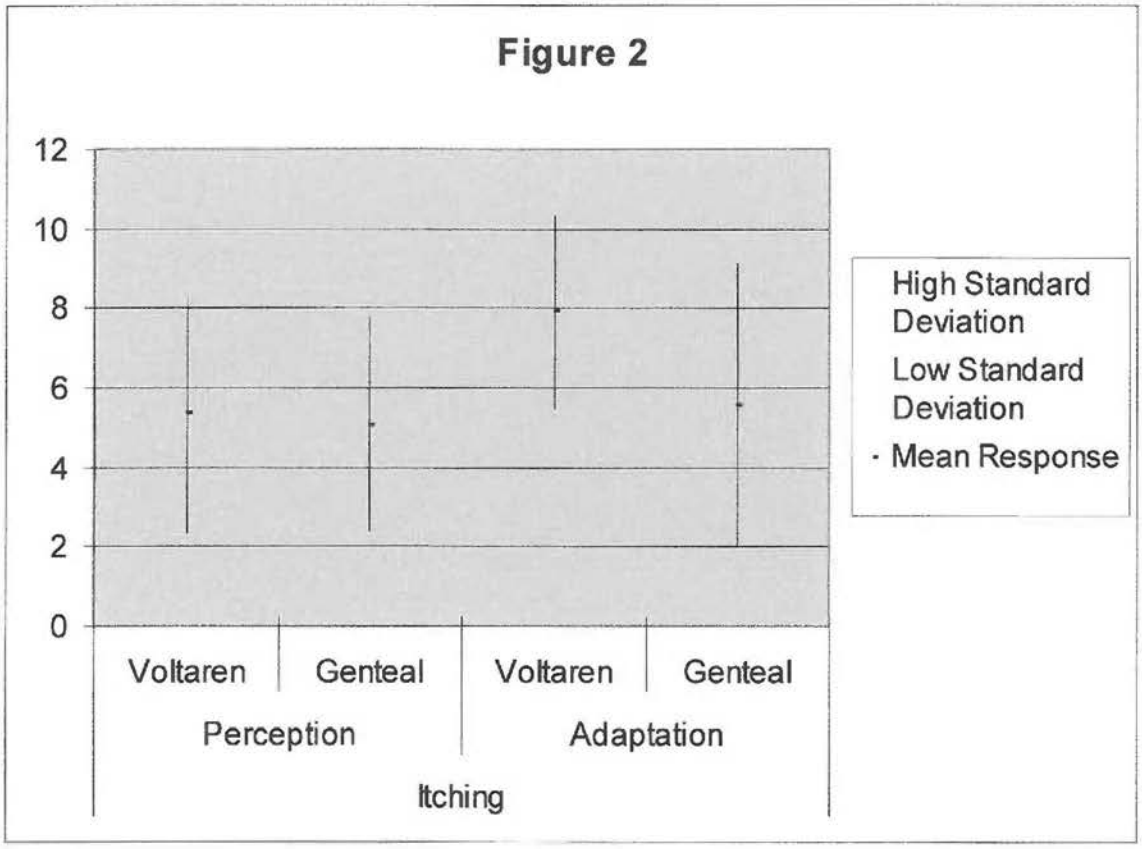
Perception
Adaptation
Dryness
High Standard Deviation
Low Standard Deviation
Mean Response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Perception
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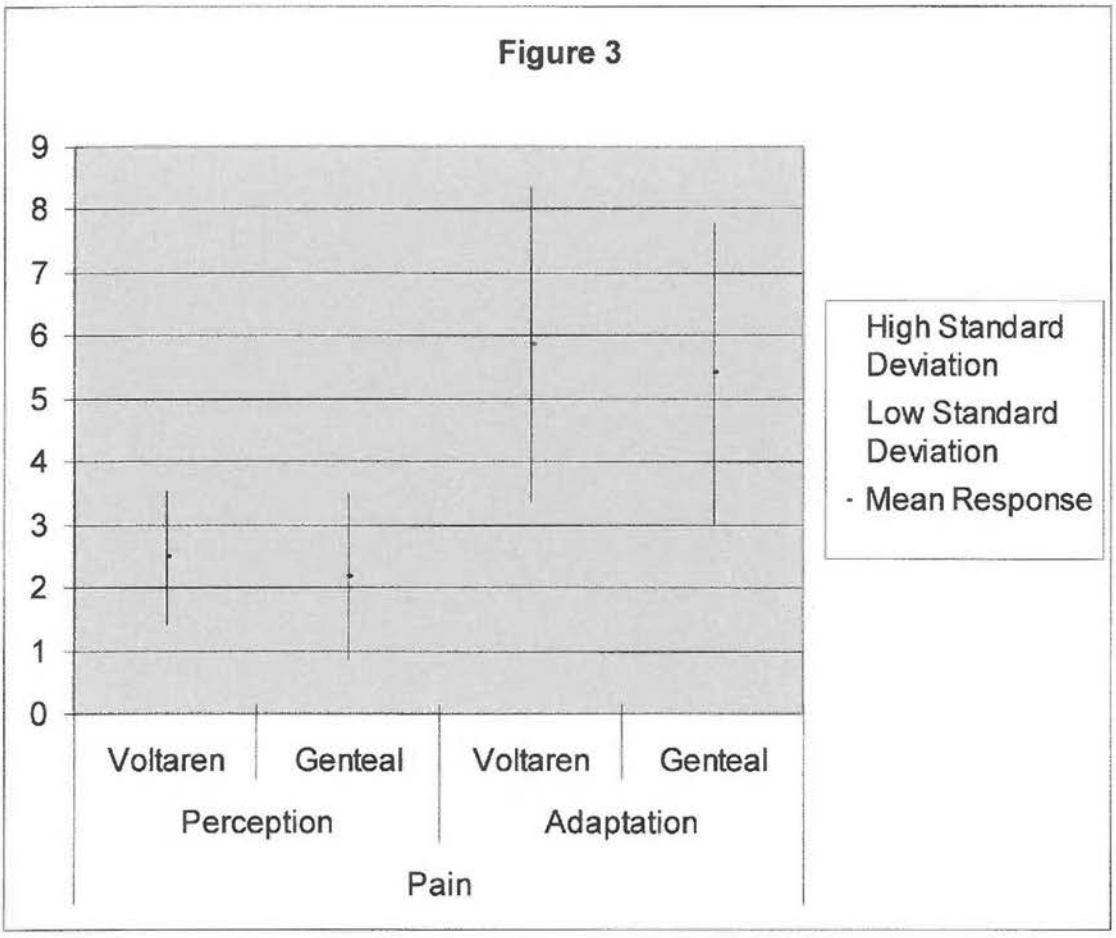
Itching
High Standard Deviation
Low Standard Deviation
Mean Response

Figure 3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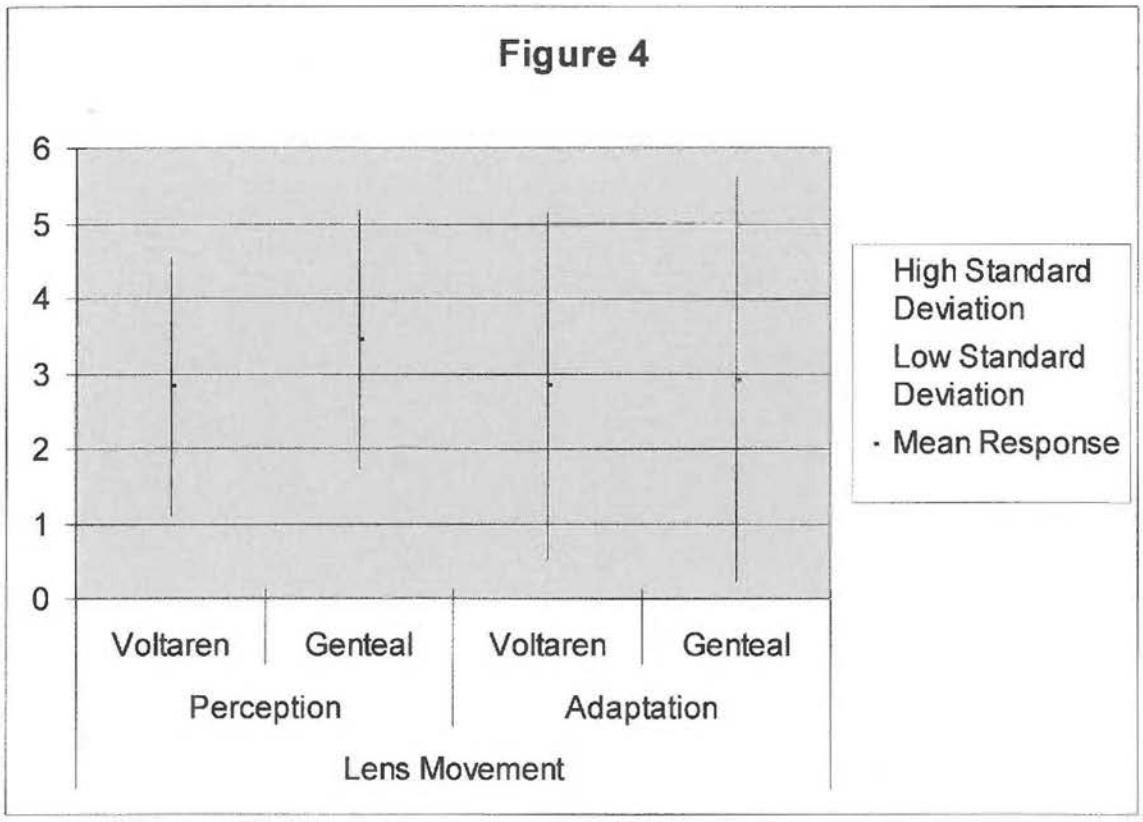
Mean Response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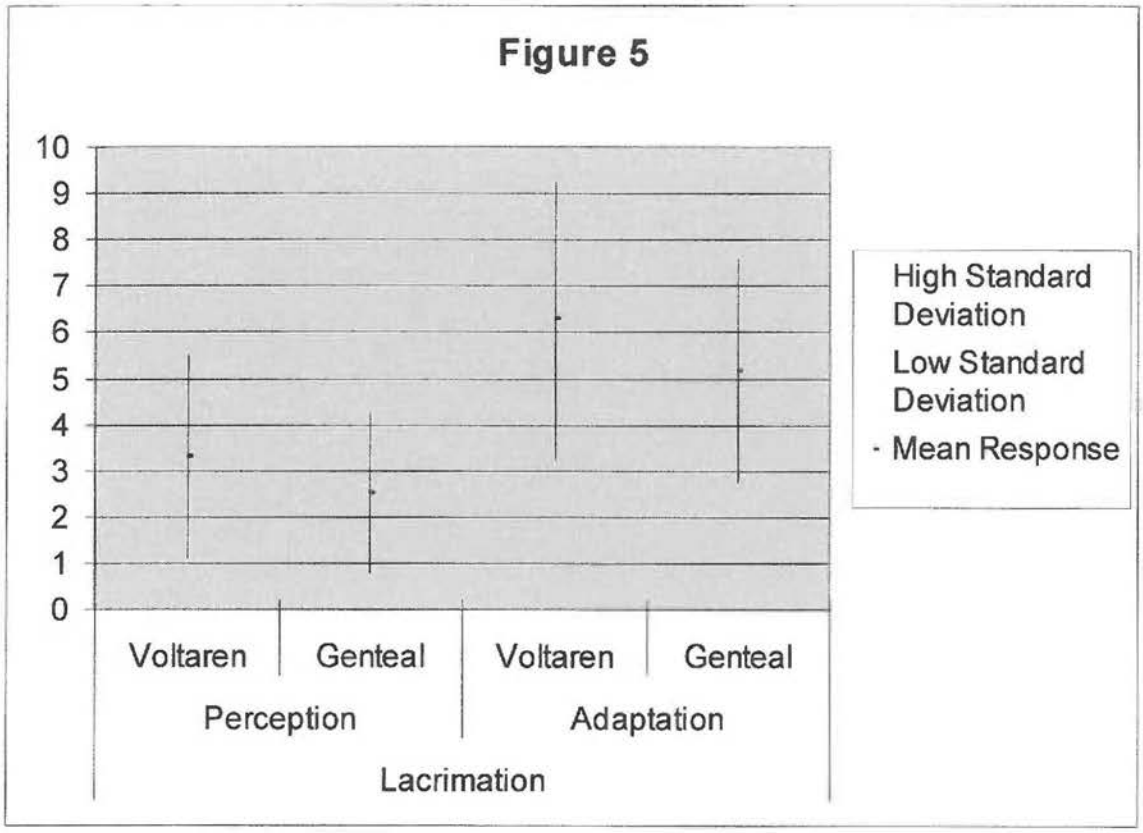
Low Standard Deviation
Mean Response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Lacrimation
High Standard Deviation
Low Standard Deviation
Mean Response

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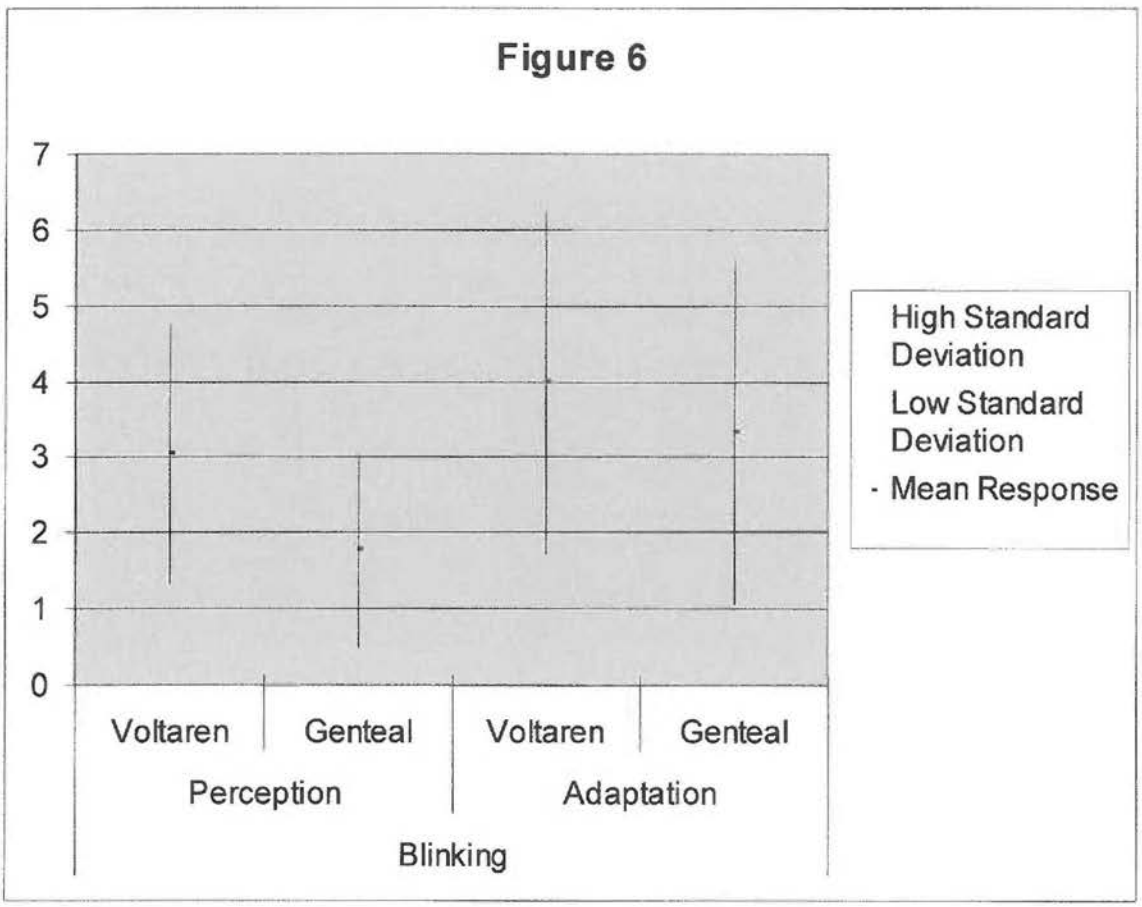
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Blinking
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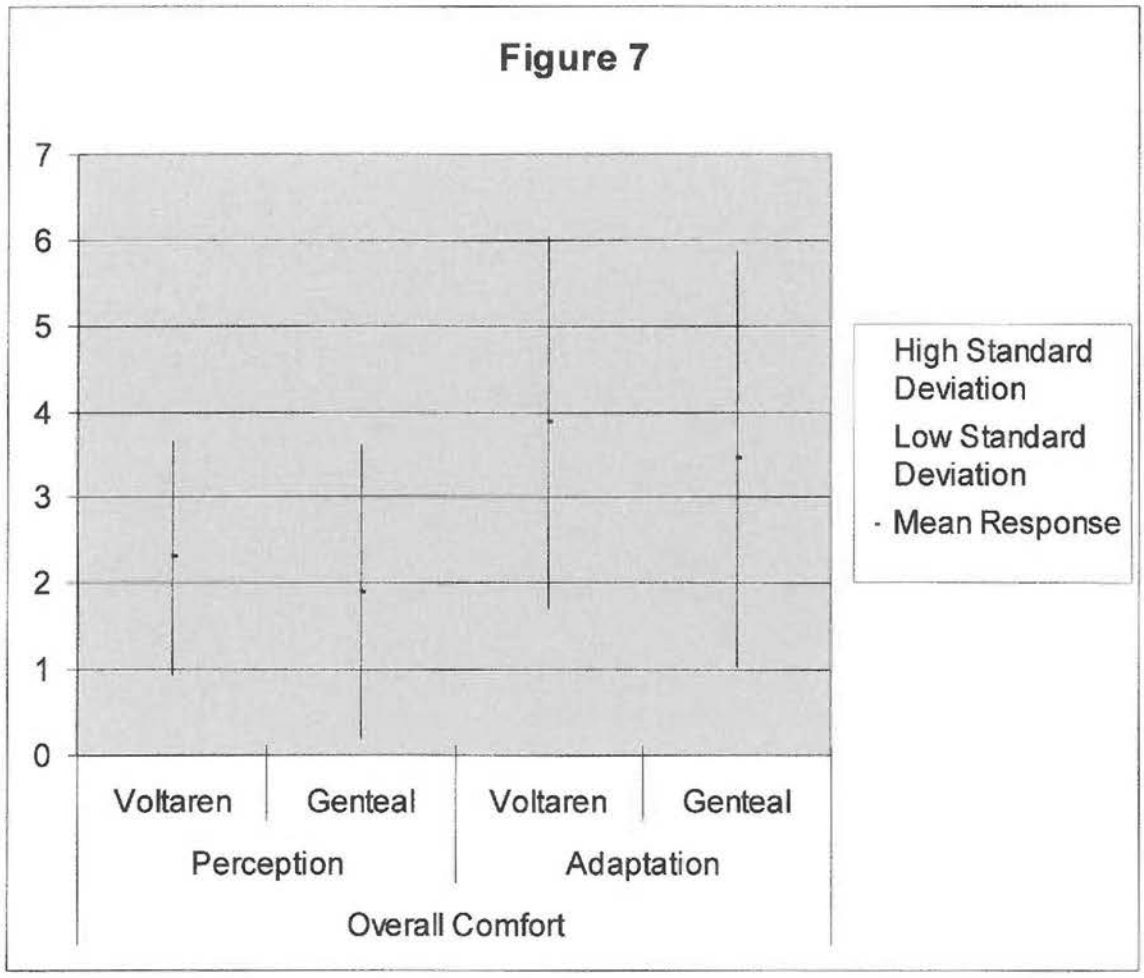
Low Standard Deviation
Mean Response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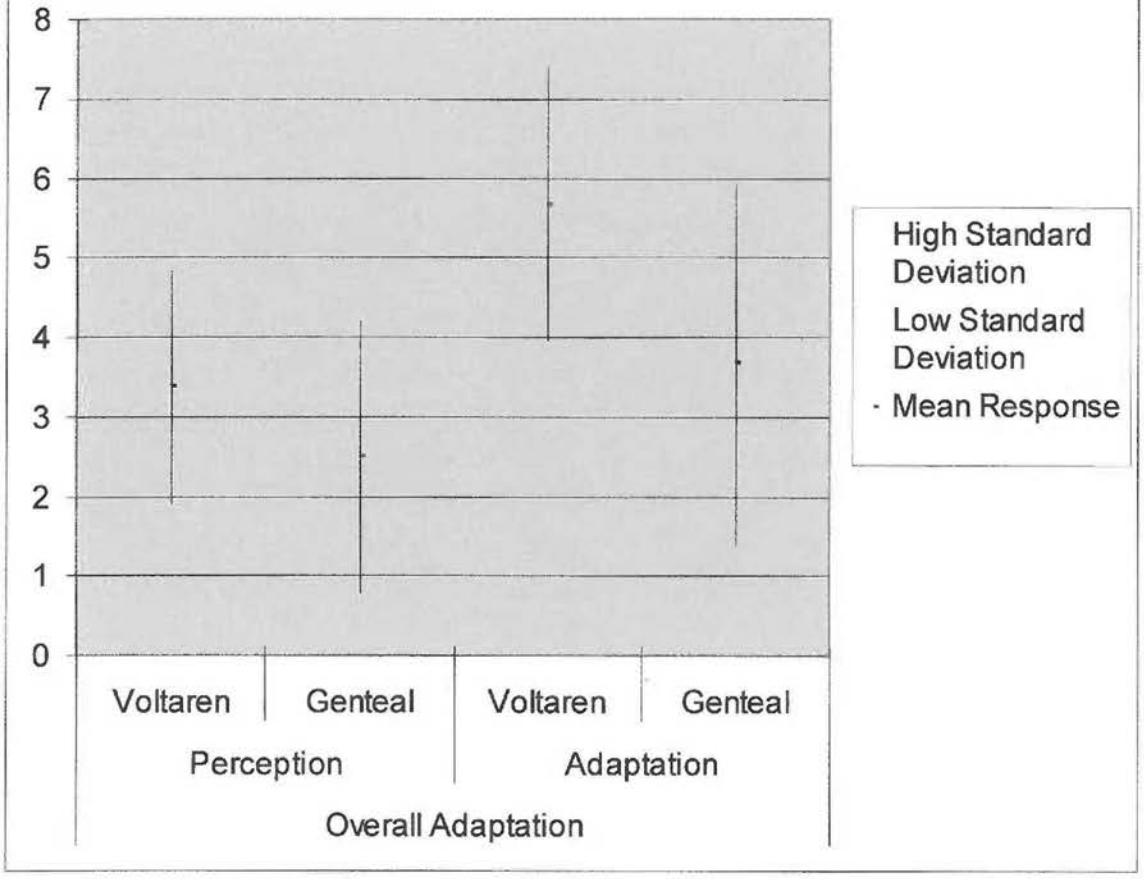
Overall Comfort
High Standard Deviation
Low Standard Deviation
Mean Response

Figure 8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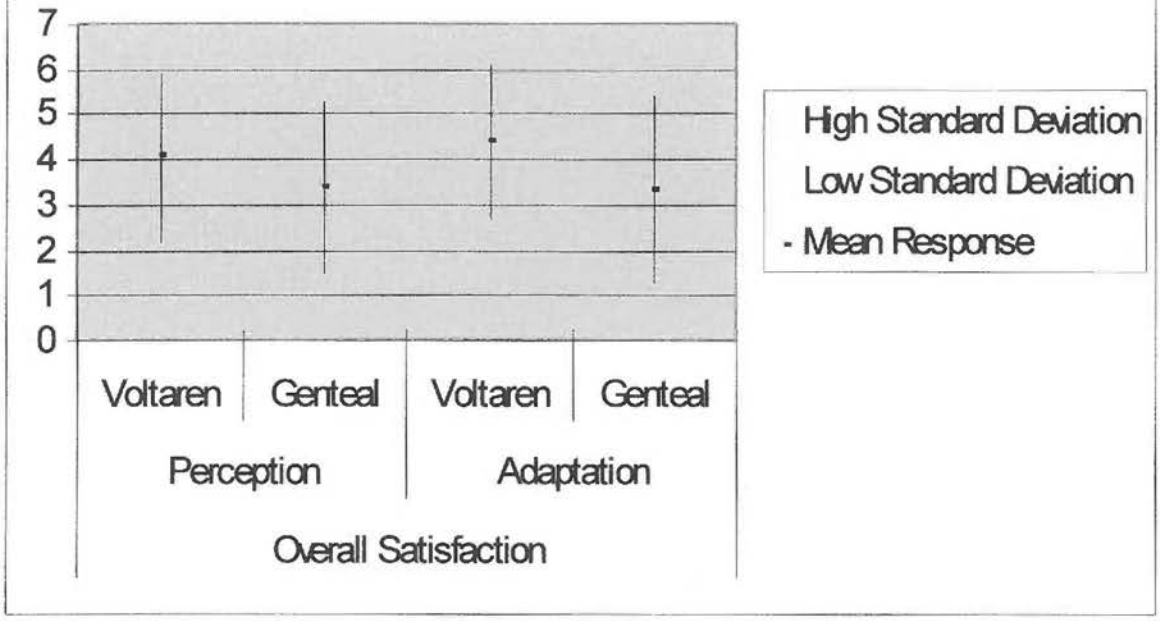
Overall Adaptation
High Standard Deviation
Low Standard Deviation
Mean Response

Figure 9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Genteal
Voltaren
Genteal
Perception
Adaptation
Overall Satisfaction
High Standard Deviation
Low Standard Deviation
- Mean Response

Perception Questionnaire

Name: _____

Date: _____

Please provide us with your anticipated perceptions to the statements below. The scales are numbered from 0 to 10, with zero indicating total disagreement and 10 indicating complete agreement with the corresponding statement. Please rate each statement by drawing a short vertical line through the scale at the point you believe corresponds with your anticipated perception of that criterion. The vertical line may be placed at any position along the scale.

My eyes will not feel dry while wearing RGP lenses

_____

0 1 2 3 4 5 6 7 8 9 10

Strongly Disagree — Strongly Agree

My eyes will not itch while wearing RGP lenses

_____

0 1 2 3 4 5 6 7 8 9 10

Strongly Disagree — Strongly Agree

My eyes will not feel pain while wearing RGP lenses

_____

0 1 2 3 4 5 6 7 8 9 10

Strongly Disagree — Strongly Agree

I will not feel lens movement while wearing RGP lenses

_____

0 1 2 3 4 5 6 7 8 9 10

Strongly Disagree — Strongly Agree

My eyes will not water while wearing RGP lenses

0	1	2	3	4	5	6	7	8	9	10
Strongly Disagree									Strongly Agree	

I will not blink more than I normally do while wearing RGP lenses

0	1	2	3	4	5	6	7	8	9	10
Strongly Disagree									Strongly Agree	

I will feel excellent overall comfort while wearing RGP lenses

0	1	2	3	4	5	6	7	8	9	10
Strongly Disagree									Strongly Agree	

I will quickly adapt to wearing RGP lenses

0	1	2	3	4	5	6	7	8	9	10
Strongly Disagree									Strongly Agree	

I will be very satisfied with my RGP lens wearing experience

0	1	2	3	4	5	6	7	8	9	10
Strongly Disagree									Strongly Agree	

Adaptation Questionnaire

Name: _____

Date: _____

Please rate the comfort of the contact lenses with respect to the criterion below. The scales are numbered from 0 to 10, with higher numbers representing greater degrees of comfort. Please rate lens comfort by drawing a short vertical line through the scale corresponding to the comfort rating. The vertical line may be placed at any position along the scale. Please make a vertical mark on the number line for each eye and print the letter R for the right eye and the letter L for the left eye above their respective marks if you are experiencing different comfort levels for each eye. If you are experiencing the same comfort level or both eyes then please make one mark on the number line and print the letter B above the line.

Please rate the sensation of dryness associated with lens wear

_____

0 1 2 3 4 5 6 7 8 9 10

Extreme dryness No dryness

Please rate the sensation of itching associated with lens wear

_____

0 1 2 3 4 5 6 7 8 9 10

Extreme itching No itching

Please rate the sensation of pain associated with lens wear

_____

0 1 2 3 4 5 6 7 8 9 10

Extreme pain No pain

Please rate the foreign body sensation (FBS) associated with lens wear

0 1 2 3 4 5 6 7 8 9 10
Extreme FBS No FBS

Please rate the amount of tearing associated with lens wear

0 1 2 3 4 5 6 7 8 9 10
Extreme tearing No tearing

Please rate the amount of blinking associated with lens wear

0 1 2 3 4 5 6 7 8 9 10
Extreme blinking No blinking

Please rate the overall comfort of the contact lenses

0 1 2 3 4 5 6 7 8 9 10
Extreme discomfort Very comfortable

Please rate the overall adaptation to the contact lenses

0 1 2 3 4 5 6 7 8 9 10
No adaptation Excellent adaptation

Please rate your overall satisfaction with the contact lenses

0 1 2 3 4 5 6 7 8 9 10
Extremely dissatisfied Very satisfied